



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Advanced Therapies

EMA warns against using unproven cell-based therapies

EMA's Committee for Advanced Therapies (CAT) is advising patients and the general public against using unregulated cell-based therapies which may not be safe or effective.

The CAT's advice is in response to individuals, companies and hospitals promoting unproven cell-based therapies as cures for a broad range of conditions including cancer, cardiovascular diseases, autism, cerebral palsy, muscular dystrophy and vision loss. These treatments can pose serious risks to patients for little or no benefit.

Patients using unproven or unregulated cell-based therapies have reportedly suffered serious, sometimes fatal, side effects including infections, unwanted immune reactions, tumour formation, loss of vision and bleeding in the brain.

Cell-based therapies are treatments using cells from the patient or a donor. The use of blood and cells for transplantation is a well-established medical practice. However, if cells are not used for the same essential function in the recipient as in the donor or if they are being substantially manipulated, they are not considered transplants and their safety and benefits cannot be assumed. For this reason, such therapies are regulated in the EU as medicinal products.

Rapidly evolving technology in the field of cell-based therapy brings exciting new opportunities for treating a range of diseases, including many currently considered incurable.

The CAT emphasises that for patients to benefit from the promise of cell-based therapies, well designed clinical trials on the safety and benefits of cell-based therapies are essential. Such trials are not only necessary for understanding the safety and benefits of innovative therapies, they also protect the safety, dignity and rights of patients. Well-designed clinical trials also keep patients informed about the potential benefits and risks of the treatments and can be used to support authorisation in the EU, which will ultimately benefit more patients.

When evaluating the data arising from clinical trials of cell-based medicines, the CAT also checks that the quality of these products is properly controlled. Once the products are authorised in the EU, EMA and national medicines authorities monitor their safety continuously and share information to enable them take rapid EU-wide decisions to protect patient's health.

Circumventing the marketing and clinical trial authorisation procedures makes it difficult to understand and document the effects of cell-based therapies, thereby depriving future patients of access to potentially curative treatments.

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The CAT will continue its work in helping the development of new cell-based and other advanced therapies with the goal of increasing timely access to these potentially life-changing treatments.

Patients or their families who are considering cell-based therapies should ask their healthcare professional about the benefits and risks of the treatment and which authority has approved it. They can also contact their national medicines authority or EMA directly.